

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re:) CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY) CA No. 07-10248-PBS
AVERAGE WHOLESALE PRICE) MDL No. 1456
LITIGATION) Pages 1 - 49

MOTION HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
November 5, 2007, 4:00 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
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1 A P P E A R A N C E S:
 2 For the Plaintiffs:
 3 GEJAA T. GOBENA, ESQ., United States Department of
 Justice, Civil Division, Commercial Litigation, Fraud,
 4 601 D Street, N.W., Washington, D.C., 20004.
 5 JAMES JOSEPH BREEN, ESQ., The Breen Law Firm,
 5755 North Point Parkway, Suite 39, Alpharetta, Georgia,
 6 30022.

7 For the Defendants:

8 JAMES R. DALY, ESQ., Jones Day,
 9 77 West Wacker, Chicago, Illinois, 60601-1692,
 for Abbott Laboratories.

10 ALSO PRESENT:

11 LAURIE A. OBEREMBT, ESQ., United States Department of
 12 Justice, P.O. Box 261, Ben Franklin Station, Washington,
 D.C., 20044.

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1 MR. DALY: Aciclovir.
 2 THE COURT: Aciclovir.
 3 MR. DALY: Well, Aciclovir, Judge, yes, and if you
 4 went our way on that issue, it would only be around -- you'd
 5 go six years back from when they brought it in, which would
 6 actually -- actually, Aciclovir, if you went that way, Judge,
 7 would probably still be out because they filed Aciclovir in
 8 June of '07. You go back six years --

9 THE COURT: Who -- did you dream up the R1-G2?
 10 MR. DALY: Well, we struggled with how to define
 11 these things and --

12 THE COURT: It's unbearably complicated the way
 13 you've briefed it, so I'm not even sure I completely
 14 understand the sequence of events. But let me start off: I
 15 don't want to waste time on whether it's the first amended
 16 complaint or the second amended complaint because either way
 17 I would give them leave to move to file. I think you've got
 18 a good argument that it really is the second one because if
 19 you take the Baylor case, the complaint in intervention is
 20 really an amended complaint. That's what gives them the
 21 relation back, and I've bought that.

22 But so what? So they move for leave to amend, and
 23 I allow it. So maybe they technically should have filed a
 24 motion. Let's get to point two: What does that do?

25 MR. DALY: Which point is that, your Honor?

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1 P R O C E E D I N G S

2 THE CLERK: In re: Pharmaceutical Industry Average
 3 Wholesale Price Litigation, Civil Action No. 01-12257, will
 4 now be heard before this Court. Will counsel please identify
 5 themselves for the record.

6 MR. GOBENA: Gejaa Gobena on behalf of the United
 7 States.

8 THE COURT: No, you have to speak up.

9 MR. GOBENA: Sorry. Gejaa Gobena on behalf of the
 10 United States.

11 MR. BREEN: Jim Breen representing Ven-A-Care of
 12 the Florida Keys.

13 MR. DALY: Good afternoon, your Honor. Jim Daly on
 14 behalf of Abbott Labs.

15 THE COURT: So instead of watching the Patriots-
 16 Colts game last night, I decided to wade through this
 17 impenetrable mess in terms of the timing of all these
 18 complaints. So I guess you are the moving party. As I
 19 understand it, no matter what happens here, this case doesn't
 20 go away. It's a question of dealing with one drug and a
 21 bunch of NDCs, right?

22 MR. DALY: Correct, Judge. I think, even if you
 23 went all our way, there would still be about a year left, but
 24 it would whittle it down substantially.

25 THE COURT: Of Aciclovir. How do you pronounce it?

1 THE COURT: Which is, let's assume they move for
 2 leave to amend for a second amended complaint. In other
 3 words, they don't do it as a matter of right. I would
 4 probably allow them to do it, and then the question is, well,
 5 what does it relate back to? But then your point is that
 6 there was nothing to --

7 MR. DALY: There's nothing to intervene on, Judge.

8 THE COURT: Intervene on. So don't waste time on
 9 whether it's the first or second amended complaint.

10 MR. DALY: All right, your Honor, I understand
 11 that.

12 THE COURT: That won't get us very far.

13 MR. DALY: Do we pick it up right there?

14 THE COURT: Yes. So then they've got the statute
 15 which says you need the express consent of the Attorney
 16 General. And your basic argument is that the declination is
 17 tantamount to a written consent.

18 MR. DALY: Right. They came in and specifically
 19 indicated they were not intervening in the other drugs, were
 20 intervening on these four drugs, which are 41 NDCs. And then
 21 Mr. Breen on behalf of the relator came in and said, "You
 22 know what? We're going to file our amended complaint by
 23 adopting the United States' complaint."

24 THE COURT: Put him aside for a minute. Do you
 25 have any case that says declining to intervene is the same

<p style="text-align: right;">Page 6</p> <p>1 thing as written consent to drop?</p> <p>2 MR. DALY: I don't think we have a case that says</p> <p>3 specifically that, Judge, but where would we be if that's not</p> <p>4 the case? In other words, what is being intervened in? I</p> <p>5 mean, when we tried to get the file in this case, for</p> <p>6 example, they kept telling us, before the Court ordered them</p> <p>7 to turn it over, that "Oh, all that stuff in the past doesn't</p> <p>8 matter. You don't have to get that because all that relates</p> <p>9 to Abbott is in this new complaint, our complaint in</p> <p>10 intervention that we, the United States, have filed and the</p> <p>11 relator has adopted as its amendment." Once that happened,</p> <p>12 there's nothing in the -- there's nothing in the netherworld</p> <p>13 of claims sitting around waiting to jump out at, because</p> <p>14 where would they go? Do they go to you?</p> <p>15 THE COURT: The statute says "express consent." So</p> <p>16 I see so many of these. We're whistleblower heaven here. So</p> <p>17 what ends up happening is, they agree to intervene on some</p> <p>18 claims and not on others. And I've had that in Neurontin.</p> <p>19 There's a bunch of them that that's happened on.</p> <p>20 MR. DALY: Right.</p> <p>21 THE COURT: Or they decline to intervene at all.</p> <p>22 You couldn't say that was tantamount to consent that they can</p> <p>23 dismiss, I mean, because I think the theory at the end of the</p> <p>24 day is -- maybe it's because the resources of the local U.S.</p> <p>25 Attorney's office doesn't permit them to, or maybe they're</p>	<p style="text-align: right;">Page 8</p> <p>1 of nightmare about this. There was no express consent to</p> <p>2 drop. As I understand it, the relator dropped, dropped it.</p> <p>3 MR. DALY: Right.</p> <p>4 THE COURT: And the government didn't protest, in</p> <p>5 fact seemed to go along with it, so --</p> <p>6 MR. DALY: They served me with the papers.</p> <p>7 THE COURT: I understand that, but I don't know</p> <p>8 what that means. I think in the statute, doesn't it say</p> <p>9 "express consent"?</p> <p>10 MR. DALY: I'm not sure of the exact language. I</p> <p>11 think it does talk about consent, but I think that if</p> <p>12 you're --</p> <p>13 THE COURT: It's a mess.</p> <p>14 MR. DALY: -- if you're co-plaintiff, the relator</p> <p>15 that you're joined at the hip with says, "I'm dropping all</p> <p>16 these claims and I'm adopting your complaint as my new</p> <p>17 amended complaint," all those things go away. And I don't</p> <p>18 know -- as I say, I'm trying to raise a practical problem --</p> <p>19 who has control over those claims? Is it you?</p> <p>20 THE COURT: I hope not.</p> <p>21 MR. DALY: I don't think the Court thinks that</p> <p>22 you've got this big brown bag of claims that nobody's ever</p> <p>23 seen before, and I don't think Judge Gold thinks that</p> <p>24 either. And I think that the reason that we all think that</p> <p>25 is because when they came out of the box in 2006, they said,</p>
<p style="text-align: right;">Page 7</p> <p>1 not sure yet, or whatever it is -- no one has said that that</p> <p>2 means that they can dismiss, "they," the relator.</p> <p>3 MR. DALY: Well, but they did, and this wasn't done</p> <p>4 in secret. I mean, they were joined at the hip when they</p> <p>5 opened this thing up in Florida, and then we transferred it</p> <p>6 here. It's not as if the government is saying that "Oh, we</p> <p>7 weren't --" they served us with those papers. They said,</p> <p>8 "Here's our intervention, and here's the relator's adoption</p> <p>9 of our complaint as the new complaint," period, end of</p> <p>10 story. I don't think there's anything to go back to.</p> <p>11 Who has these claims; in other words, these claims</p> <p>12 that they're just sort of picking out of this bottomless pit</p> <p>13 of claims?</p> <p>14 THE COURT: You're right, the relator dropped it.</p> <p>15 You're right, the relator dropped it. And then the question</p> <p>16 is, so did they validly drop it?</p> <p>17 MR. DALY: But where are they? In other words, do</p> <p>18 they go to you? Do they go to Judge Gold in Florida? I</p> <p>19 mean, they've continually told us throughout this litigation</p> <p>20 that "There's nothing left in Florida. Everything we have to</p> <p>21 say about Abbott is in this complaint and in front of</p> <p>22 Judge Saris in Boston. You don't need to see the file. You</p> <p>23 don't need to --"</p> <p>24 THE COURT: I agree it's as sloppy as it gets, but</p> <p>25 also there's also the statute, so that's what creates a sort</p>	<p style="text-align: right;">Page 9</p> <p>1 "This is our complaint in intervention. This is our amended</p> <p>2 complaint."</p> <p>3 THE COURT: I forgot to look it up. Does the</p> <p>4 statute say "express consent," or does it say --</p> <p>5 MR. GOBENA: It says "express written consent from</p> <p>6 the court and the United States."</p> <p>7 THE COURT: So that's the problem you run into is</p> <p>8 the statute. So the problem is, you're right, I mean, they</p> <p>9 botched it up procedurally, but I don't have express written</p> <p>10 consent. I have implied.</p> <p>11 MR. DALY: Well, you do have by the court. It says</p> <p>12 "by the court and the Attorney General." But the court</p> <p>13 approved it, and they allowed the relator to amend by</p> <p>14 adopting the United States' complaint. I mean, that's clear</p> <p>15 as a bell.</p> <p>16 THE COURT: You certainly have implied consent, but</p> <p>17 you don't have express written consent is the problem. I</p> <p>18 don't know where that leaves you.</p> <p>19 MR. DALY: Well, and, you know, if you want to talk</p> <p>20 about the statute, another thing I want to emphasize with the</p> <p>21 Court is, for them to intervene on something like this, they</p> <p>22 need good cause. The U.S. can intervene on a claim if</p> <p>23 they've got good cause. I don't think there's anything to</p> <p>24 intervene on because these claims weren't there, you know, in</p> <p>25 June of this year when they intervened on it. But even if</p>

1 they were, what is it that the government tells us is their
 2 reason for wanting to come into this case? They say, "Oh, we
 3 have new evidence concerning Aciclovir." And I don't know if
 4 the Court had a chance to look at --

5 THE COURT: I know, but I can't decide that on a
 6 motion to dismiss. That's like a summary judgment motion.

7 MR. DALY: Well, except that the things that they
 8 say are new were attached to the complaint in 1997. In other
 9 words, there's nothing new about Aciclovir in this new
 10 complaint. The letter that they talk about and the
 11 allegation that somebody at Abbott said, "We're going to
 12 widen the spread," that is in the complaint that the relator
 13 filed in 1997. It's the relator's third --

14 THE COURT: And why is that relevant? Because?

15 MR. DALY: Because this isn't new. This notion
 16 that there's new evidence that they found that they want to
 17 bring these Aciclovir claims has completely unraveled. The
 18 very allegations that they make in this new complaint were in
 19 the complaint filed by the relator in 1997, in the R-3
 20 complaint.

21 THE COURT: Why is that relevant?

22 MR. DALY: Because they said that they're entitled
 23 to do this because they have new evidence. There is no new
 24 evidence. The evidence is ten years old.

25 THE COURT: This is such a complicated set of

1 MR. DALY: Well, the reason it's ten years later is
 2 that ten years have gone by. You know, we've been prejudiced
 3 by this. We've had a year and a half of discovery. Our
 4 discovery period ends in two months. We've been working away
 5 on this. Every request we make --

6 THE COURT: All right, so this is just about a
 7 tardy amendment is what you're saying.

8 MR. DALY: Well, that's one of our arguments.

9 THE COURT: You know, it's like the typical
 10 Rule 15(a) kind of discussion.

11 MR. DALY: Correct, and I also think that then you
 12 look at why are they saying we're bringing this. When they
 13 first come to the court, they say, "We're bringing it because
 14 we have new evidence." We looked at the new evidence, and we
 15 found out that the new evidence that they cite was attached
 16 to the complaint that was filed in 1997. There is no new
 17 evidence on this.

18 THE COURT: Assume you're right, there's no new
 19 evidence. Why can't --

20 MR. DALY: So they have no reason for not -- the
 21 decision to do this when they opened up against us in 2006
 22 was conscious. This isn't some mistake.

23 THE COURT: That happens every day of the week on a
 24 motion to amend. So what you're really saying is that you
 25 should get -- I shouldn't do it because you're prejudiced.

1 briefings. Let me just get this. If leave to amend is
 2 liberally granted, and assume for a minute there was not
 3 express written consent from the Attorney General so the
 4 claim is still out there in the netherlands, why can't they
 5 just amend?

6 MR. DALY: Because I think under the False Claims
 7 Act, they still need good cause, and I think the Court has to
 8 look --

9 THE COURT: Good cause to?

10 MR. DALY: To intervene and pick up these claims
 11 that they say are out there, and I think the Court has to
 12 look --

13 THE COURT: Normally they don't have to show good
 14 cause to intervene, do they?

15 MR. DALY: It's in the statute. Sure.

16 THE COURT: They just intervene, I mean --

17 MR. DALY: Well, then they have to have good cause
 18 to do so, and the Court has to look at that.

19 THE COURT: You mean good cause to intervene late?

20 MR. DALY: Well, I think late and at all. I mean,
 21 the problem here is that the stuff that -- they came to the
 22 court and they --

23 THE COURT: They have good cause to intervene, but
 24 you're saying if -- they had it ten years ago, so why does it
 25 matter that it's ten years later?

1 MR. DALY: That's one of our arguments, yes,
 2 Judge. And I also think that we do have this metaphysical
 3 problem of, what are they intervening in? There is no
 4 Aciclovir claim for them to intervene on. If they want to
 5 sue us, "they," if the government wants to sue Abbott for
 6 Aciclovir, they can bring it under 3730(a), which is the
 7 direct action.

8 THE COURT: Right, and it gives them a year.

9 MR. DALY: It gives them six years.

10 THE COURT: No, I understand. It gives them --

11 MR. DALY: Six years from today, or from whenever
 12 they filed it in June.

13 THE COURT: Right, and you said that simply means a
 14 year of recovery, right?

15 MR. DALY: Well, because they allege in their
 16 complaint that the alleged scheme ended in April of 2001, so
 17 it effectively does that. But that's their option at this
 18 point, and I don't think you can sort of resurrect claims
 19 that have been abandoned and call it an intervention.

20 THE COURT: I don't know, so why don't I turn to
 21 you and ask. This is a mess procedurally, okay? So let me
 22 just start you from point one, which is, you can't say that
 23 you can relate back and not say that the complaint in
 24 intervention is tantamount to an amended complaint. You just
 25 can't have it both ways. If it's a brand-new complaint, then

<p style="text-align: right;">Page 14</p> <p>1 it doesn't relate back. I mean, you can't have your cake and 2 eat it too on the procedural argument. So I bought your 3 argument essentially that it was essentially an amended 4 complaint and it relates back under the first prong.</p> <p>5 MR. GOBENA: 15(c)(1).</p> <p>6 THE COURT: 15(c)(1). So you need to move to 7 amend, and I'll say that from now on, because this whole area 8 has suddenly turned into a mess.</p> <p>9 MR. GOBENA: Sure.</p> <p>10 THE COURT: So now the part that I was struggling 11 with last night is, the statute says you have to have written 12 consent of the Attorney General, but you guys just sat by 13 while they dropped it. What do I do with that? He's 14 technically correct, there's nothing to intervene in. Do I, 15 like, just like Lazarus... emerging? I'm not blaming you 16 personally. It is messy.</p> <p>17 MR. GOBENA: I understand your Honor's concern, and 18 I think the key is that there is a distinction between, I 19 think, essentially dropping something and dismissing 20 something. I mean, FCA claims can only be dealt with if 21 they're dismissed. You can't just abandon them.</p> <p>22 THE COURT: He dismissed it, didn't he?</p> <p>23 MR. GOBENA: No. What he did was, he adopted the 24 United States' complaint in intervention as the relator's 25 complaint; didn't move to dismiss it; just asked for the</p>	<p style="text-align: right;">Page 16</p> <p>1 THE COURT: So they amended by adding maybe. So 2 they didn't actually dismiss their complaint?</p> <p>3 MR. DALY: They amended it by dropping everything 4 that they had that wasn't -- they simply adopted as their 5 complaint the government's complaint, and whatever they 6 had --</p> <p>7 THE COURT: Didn't they technically dismiss out 8 their --</p> <p>9 MR. DALY: I don't think it was a motion to 10 dismiss, Judge, no.</p> <p>11 THE COURT: It's a disaster.</p> <p>12 MR. DALY: One thing I will point out is, the 13 statute says dismiss "actions" without consent, not 14 "claims." The action hasn't been dismissed, but I don't 15 think there's any prohibition on dismissing claims without 16 the Attorney General's consent.</p> <p>17 THE COURT: A new argument you must have just 18 thought of.</p> <p>19 MR. DALY: Well, I meant to say it, Judge, but I 20 moved on.</p> <p>21 MR. GOBENA: Of course, the United States believes 22 that's drawing too fine a line between what the statute was 23 really trying to get at. I mean, the issue is that, and this 24 will be made very clear --</p> <p>25 THE COURT: Are there any cases on this at all in</p>
<p style="text-align: right;">Page 15</p> <p>1 Court to allow for an amendment to adopt the United States' 2 complaint, so --</p> <p>3 THE COURT: Did somebody allow his motion to 4 dismiss?</p> <p>5 MR. GOBENA: The court did.</p> <p>6 THE COURT: Is that me?</p> <p>7 MR. GOBENA: No, not you. It was Judge Gold down 8 in Florida.</p> <p>9 THE COURT: Right, so they were dismissed. So, I 10 mean, he's technically correct, there's nothing to intervene 11 in.</p> <p>12 MR GOBENA: Well, it wasn't a motion to dismiss, 13 your Honor, and that's the thing. They didn't ask to have 14 their claims eliminated. All they asked to do is to adopt 15 the United States' complaint by amendment.</p> <p>16 THE COURT: So they did move to dismiss down there?</p> <p>17 MR GOBENA: No. There's no motion to dismiss, and 18 certainly if there's a motion to dismiss, the United 19 States --</p> <p>20 THE COURT: Do you agree with that, there's no 21 motion -- that the claims haven't been dismissed?</p> <p>22 MR. DALY: No, I don't. There's no "motion to 23 dismiss," but they amended by adopting. So whatever I had 24 before I don't have because I'm jumping in with the United 25 States on their complaint.</p>	<p style="text-align: right;">Page 17</p> <p>1 the United States of America?</p> <p>2 MR. GOBENA: No, not specifically, but there's some 3 general case law that I think guides the Court. I mean, 4 there's a Sixth Circuit decision, U.S. Ex Rel Taxpayers 5 Against Fraud V. General Electric; and one of the things the 6 court said there, and admittedly it's in dicta, is that the 7 False Claims Act has been crafted in such a way with such 8 particular care as to give the United States primacy when it 9 comes to overseeing the prosecution of False Claims Act 10 claims, regardless of whether it brings it itself or the 11 relator brings it.</p> <p>12 So when you look at sort of where all the courts 13 are going in terms of the United States' control over False 14 Claims Act action, the only logical conclusion is that you 15 have to read the statute on the basis of its plain meaning.</p> <p>16 And Congress intended both the court and the United States to 17 get (Inaudible) consent to dismissal. If the relator then 18 decided to move to dismiss, we certainly would have 19 considered the motion and done whatever was appropriate based 20 on our evaluation of the motion and the claims, but we 21 weren't presented with that situation.</p> <p>22 And just to go back a moment, I don't want to waste 23 the Court's time too much on this, but on the issue of 24 Aciclovir, we had allegations in 1997 from the relator about 25 Aciclovir. It's a mega-spread drug. It's a drug with</p>

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1 spreads, I think eventually over a thousand percent. And we
 2 had allegations from one customer, particularly the relator,
 3 who claimed that Abbott's salespeople were marketing the
 4 spreads to them. And we didn't intervene at that time
 5 because we wanted to get some verification in discovery, and
 6 in the course of discovery we took a deposition of the
 7 salesperson who was alleged to have done it, and he confirmed
 8 he talked about AWPs with the relator. And to talk about
 9 AWPs is the functional equivalent of talking about the
 10 spreads, so that's the new --

11 THE COURT: Why did it take ten years?

12 MR. GOBENA: Are you talking sort the macro sense
 13 to investigate the cases or with respect to this particular
 14 drug?

15 THE COURT: This case.

16 MR. GOBENA: Well, to be honest with you, I can't
 17 give you the history beyond 2004 because I wasn't on the
 18 case. So all I can do is roll it up in the larger issue,
 19 which is, you know, when these cases were brought in Florida,
 20 there were some thirty or forty defendants out there, and
 21 tens of thousands of NDCs are being investigated, and the
 22 government did its best with the limited resource it had to
 23 sort through defendants. And over time, we've settled
 24 cases. There's been over a half a million dollars' worth of
 25 settlements in these Ven-A-Care cases, and we've intervened

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1 in some, and we've dismissed a bunch actually. So we do
 2 actually dismiss cases when it makes sense to do so.

3 So why it took ten years specifically about
 4 Aciclovir? I can't tell you, but I can tell you sort of
 5 generally why this case has taken so long. And one of the
 6 difficulties we've had, your Honor, is that, you know, we
 7 issued investigative subpoenas in these cases back in 19 --

8 THE COURT: -- the only reason it took you ten
 9 years to get the confirmation of the positions is because it
 10 took you that long to notice the depositions.

11 MR. GOBENA: Fair enough.

12 THE COURT: As I understand it. It's not your
 13 typical newly discovered evidence.

14 MR. GOBENA: Right, I think that's right. I mean,
 15 but -- well, we (Inaudible) the ability to compel testimony,
 16 sworn testimony about -- well, I guess we did under civil
 17 investigative demand provisions, but, you know, obviously we
 18 took the route of getting the sworn testimony through
 19 litigation. And the ten years is a function of the fact that
 20 the investigation was complex. It involved many more
 21 defendants than Abbott. So it's unfortunately why it took so
 22 long.

23 However, I don't think it outweighs the fact that
 24 we're talking about a mega-spread drug. We're talking about
 25 the fact that their salespeople were going out there and

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1 marketing it. This was a very powerful antiviral drug. It's
 2 used to treat AIDS patients. I mean, it's not a drug that --
 3 you know, it's not just the typical generic out there. It
 4 was generic. However, it served an important function, so I
 5 think that the, you know, the sort of justice weighs in favor
 6 of allowing us to have this amendment to add a drug.

7 THE COURT: Going back to his point, assume you're
 8 absolutely correct --

9 MR. GOBENA: With respect to the consent?

10 THE COURT: -- that you need the written consent of
 11 the Attorney General, and they didn't get it, but still
 12 there's nothing there right now to intervene in. So what
 13 does one do?

14 MR. GOBENA: Oh, I argue, your Honor, that there
 15 actually is something there to intervene in, which is that,
 16 you know, while the relator may have a Fifth Amendment
 17 complaint that adopts the United States' complaint in
 18 intervention, it didn't dismiss, you know, the NDCs and
 19 claims that are identified in this fourth amended complaint.

20 THE COURT: You never actually, is that correct,
 21 you never actually dismissed it?

22 MR. BREEN: That's correct, your Honor.

23 MR. GOBENA: So there really are --

24 THE COURT: Do I have it somewhere?

25 MR. GOBENA: You might have it as an exhibit to the

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1 motion.

2 MR. DALY: Judge, the relator's motion is Exhibit K
 3 to our original motion to dismiss here, and then Judge Gold's
 4 order is Exhibit L.

5 THE COURT: I think we have it all upstairs. So
 6 your argument would be, even because they adopted it, it
 7 doesn't mean they dismissed their own claims?

8 MR. GOBENA: I think that's correct. They have to
 9 move the Court to dismiss it. I mean, the statute talks
 10 about dismissal. It didn't talk about dropping or
 11 abandonment. I don't think abandonment or dropping is
 12 sufficient to meet the statute's requirements in terms of the
 13 disposal of a claim. So as a result, there very well are,
 14 you know, these NDCs --

15 THE COURT: Does this mean five years from now
 16 you'll find another one of these drugs and then amend and
 17 relate it back?

18 MR. GOBENA: Well, I think, you know, in this
 19 instance here, what we were trying to do is, we thought we
 20 were allowed to move and amend as a matter of right under
 21 15(a), and I understand the Court's decision about that.

22 THE COURT: So you're going to have to move to
 23 amend.

24 MR. GOBENA: We'd have to move to amend, and then
 25 the Court would have to make a decision at that point,

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1 weighing a variety of factors, as to whether or not it was
 2 appropriate to do the amendment. So there is, you know, a
 3 doorstep on this, and that's the Court's discretion and the
 4 Court's authority to decide not to grant a motion to amend
 5 down the road, although I will note that we only have two
 6 months of fact discovery left, so our ability to --

7 THE COURT: What do you do with his point, which is
 8 he has to go back through and do all this discovery again?
 9 Because, I mean, I will do a typical Rule 15 kind of
 10 balancing.

11 MR. GOBENA: Yes, well, one thing is that we put
 12 them on notice, I believe as of June, with six months left in
 13 the discovery period, that we were interested in pursuing
 14 this drug. And I actually personally sent a request for
 15 documents related to Aciclovir. They've decided not to
 16 produce it. I don't know if they're gathering it or not. On
 17 the government's side, we're trying to do our best to
 18 gather --

19 THE COURT: Does that mean you have to go back and
 20 depose all these people all over again?

21 MR. GOBENA: Well, not necessarily. If you're
 22 talking about their depositions of government people,
 23 frankly, from what I've seen, and, again, in my
 24 representation to the Court, they don't really ask
 25 drug-specific questions. Most of their defense is built on

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1 the generalized government knowledge: "You knew that there
 2 were spreads, and you still kept the system --"

3 THE COURT: Well, let's assume I make them move --
 4 well, not assume -- I am going to require them to move to
 5 amend. What are the actual now damages caused by a delay?

6 MR. DALY: Well, these two drugs are, you know,
 7 drugs that have a lot of sales, they have a lot of data, a
 8 lot of information, a lot of people that they want to
 9 depose. We obviously need to find out what the federal
 10 government knew about these drugs. One of the things that
 11 the government has, the position that they've taken in
 12 discovery is, "Gee, if it doesn't mention one of your drugs
 13 that we've sued you on, the subject drugs, we're not giving
 14 you the documents." So as far as we know, they could have a
 15 treasurer trough of documents relating to Aciclovir, and we
 16 don't have them. Obviously, we have to ask for that.

17 THE COURT: That's just additional time to do it,
 18 but what are the actual dollar damages from having to go
 19 redepose people?

20 MR. DALY: Well, if we had to do that, it would be,
 21 you know, it's certainly tens of thousands of dollars.

22 THE COURT: Why?

23 MR. DALY: Well, because we've taken probably
 24 forty, fifty depositions per side thus far. I'm not saying
 25 we'd want to go back and do them all, but I think we would be

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1 careful about what we do.

2 THE COURT: Are they in different locations and in
 3 Washington? Where are they?

4 MR. DALY: Some are in Washington. They've tended
 5 to be in various places because a lot of people have
 6 retired. Remember, some of these events are from the early
 7 to mid-'90s, so people have left the government, are in other
 8 positions or retired at this point in time, but by and large,
 9 we've been able to get them in D.C.

10 MR. GOBENA: Your Honor, if I could address that,
 11 first of all, the amount of utilization for Aciclovir from
 12 '97 to 2001, we're talking, I think, about \$400,000 or
 13 \$500,000 here. It's not a huge utilization drug.

14 Secondly, there's no J-Code for this drug, and
 15 that's because there wasn't a lot of significant Medicare
 16 utilization. I think our damages for Aciclovir are going to
 17 be Medicaid damages, and thus far they've only deposed a
 18 handful of Medicaid people at CMS that I'm aware of. I don't
 19 know that they've deposed too many state Medicaid people to
 20 the extent they --

21 THE COURT: So you're willing to pay for whatever
 22 expenses it costs to fly back and depose these people a
 23 second time?

24 MR. GOBENA: Well, I mean, your Honor, if they've
 25 not moved to dismiss -- I think that we should be allowed to

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1 add the drugs based on the conduct at issue. I don't think
 2 we should have to pay their fees in connection with it
 3 because the conduct is so egregious that we have to seek
 4 damages for (Inaudible) --

5 THE COURT: At some point the government has got to
 6 eat it. I mean, they've got to make a decision in terms
 7 of -- you know, I'm sympathetic that these are massive
 8 spreads and a huge amount of time. It's just, you know, now
 9 we're almost at the tail end of discovery. He has to go back
 10 and depose some of these people if I allow it, and the
 11 government should have to pay for whatever the actual -- not
 12 the time in the deposition because that would have happened
 13 if you'd done it in a timely way, but different travel
 14 expenses and that sort of thing.

15 Where's your firm, Mr. Daly?

16 MR. DALY: Primarily in Chicago, although we've got
 17 folks in Washington working on it as well.

18 THE COURT: The depositions are where?

19 MR. GOBENA: Well, I mean, the thing is, I don't
 20 even know who you're anticipating deposing, Mr. Daly,
 21 because, quite frankly, your Honor, as I mentioned, none of
 22 these CMS witnesses, I mean, at best a few of them that
 23 they've deposed thus far really know anything about Medicaid
 24 programs.

25 THE COURT: Oh, so it may be a very small amount of

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1 money.

2 MR. GOBENA: Exactly. I mean, I think what we need
3 to do is assess, you know, really the impact first before
4 that kind of sanction is imposed on the government for
5 amending the complaint.

6 THE COURT: It's not a sanction. It's a condition
7 for amending so late, like, two months left of the discovery
8 period. I mean, it's a typical thing that you impose on
9 parties.

10 MR. GOBENA: Well, your Honor, when we sought to
11 amend, there was six months left in discovery, and we filed
12 our first amended complaint in June. Two months was because
13 we --

14 THE COURT: You didn't have the right to just file
15 it because you needed to move to amend, and it just --

16 So I think what Mr. Daly needs to do, because he
17 talked in very general terms about his prejudice without
18 being specific, what I'd be inclined to do is to allow the
19 motion to amend when it's filed. In opposition, you should
20 essentially detail any additional expenses. I'm not talking
21 about attorneys' fees because if he had done it in a timely
22 way, you would have had to actually have done the deposition
23 anyway, but any additional cost from traveling from Chicago
24 to Washington or an additional hotel room and the like. And
25 I want to know, are any more of these things coming?

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1 MR. GOBENA: In terms of Abbott claims, claims
2 against Abbott? As far as I know, I think that's it, based
3 on the evidence we have at hand. Again, discovery has two
4 months left. I don't anticipate anything, but I'm not sure
5 in terms of adding additional drugs.

6 THE COURT: Now, what's coming in two months,
7 expert discovery?

8 MR. GOBENA: Yes, expert discovery starts at that
9 stage, although, your Honor, I would like to point out to the
10 Court, I want to give the Court advanced notice, we're two
11 months away from the end of discovery. We haven't received
12 an answer from Abbott. So we can guess at what their
13 defenses are going to be, but we haven't gotten --

14 THE COURT: When are you going to file an answer?

15 MR. DALY: Well, if the Court were to grant my
16 motion to dismiss, I'd never have to file an answer.

17 THE COURT: Well, you would on the other claims.

18 MR. DALY: As soon as the Court rules, because
19 right now our current motion is addressed to the entire
20 thing.

21 THE COURT: What are your defenses?

22 MR. DALY: A, we didn't do it, and, B, they knew
23 about it and it was part of the system.

24 THE COURT: So now you know.

25 MR. GOBENA: I guess what I'm asking the Court is

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1 that when the Court makes its decision on the motion to
2 dismiss, if it could order the answer to be served by Abbott
3 within a week of the Court's order.

4 THE COURT: How many paragraphs?

5 MR. GOBENA: In our complaint? I think it's 130.

6 THE COURT: I don't know that you can do it in a
7 week.

8 MR. GOBENA: Well, I mean, the only issue I have,
9 your Honor, is that there may be affirmative defenses in
10 there that we're going to need to do discovery on, and we're
11 going to run out of time.

12 THE COURT: He just told you what they were.

13 MR. GOBENA: Well, in general terms. I've seen
14 their answers in other cases, and they have 60 plus
15 affirmative defenses listed out there, so it's not, like,
16 that simple as he characterized it.

17 THE COURT: When can you give them a draft answer
18 so they'll know what your likely affirmative defense is?

19 MR. DALY: I mean, I could provide them something,
20 Judge, that will give them a foreshadowing of what they will
21 be. Perhaps a letter, would that be all right, Judge?

22 THE COURT: Yes. When can you file your motion to
23 amend?

24 MR. GOBENA: We can do that by the end of this
25 week.

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1 THE COURT: Fine. And you're going to respond
2 within a week, because I've got most of it here in these
3 massive filings, as to what any prejudice would be. I have
4 to look at your -- see what you technically did here to see
5 if there are any claims to still intervene in, if there was
6 an actual dismissal as opposed to just an adoption. You're
7 saying, as you see it, you remember you didn't actually
8 dismiss the --

9 MR. BREEN: Your Honor, we didn't, and just for
10 what it's worth, and granted this is a complicated case, a
11 complicated situation, there's a lot of first decisions here,
12 but here's how I see it: We pled a claim. We pled a cause
13 of action under the False Claims Act. These Aciclovir
14 allegations, we think they're allegations. We believe it was
15 the right thing to do to join the government's complaint to
16 simplify this case and not proceed on every possible NDC that
17 the relator had developed information on. But these
18 Aciclovir claims are allegations; and to the extent that
19 those allegations are not in the current complaint, it's not
20 as if we dismissed or abandoned the cause of action. They're
21 the same division, the same people, the same marketing
22 mechanisms. We're not talking about there are other
23 divisions and other drugs.

24 And I never looked at these as being a cause of
25 action or something to be dismissed. I looked at this as

1 streamlining our case, joining in the government's complaint,
 2 and making it simpler for everybody. But just like any other
 3 allegations that are still there that relate to our cause of
 4 action, to the extent that they're a proper subject to
 5 amendment, everything relates back.

6 THE COURT: It's a mess.

7 MR. BREEN: It's not like we're trying to bring a
 8 new theory or a new cause of action.

9 THE COURT: Did you ever actually dismiss your
 10 allegations involving this?

11 MR. BREEN: No, your Honor, absolutely not.

12 THE COURT: I'm going to have to go upstairs and
 13 look. Was it a motion to substitute?

14 MR. BREEN: It was a motion for leave to amend by
 15 adopting the government's complaint in intervention.

16 THE COURT: And it never says dropping the other
 17 claim?

18 MR. BREEN: I don't believe so, your Honor.

19 THE COURT: So let me just be clear now. Whatever
 20 I do here, I'll take care, I'll protect Abbott from any
 21 unnecessary expenses by flying back and taking a new
 22 deposition, or whatever, but I'm not going to grant any more
 23 motions to amend unless it's genuinely new evidence -- not
 24 "We didn't get around to taking the deposition" -- genuine.
 25 These cases have to end.

1 And what about Dey? What are all the other cases I
 2 have, Roxane? All these other things, are we going to keep
 3 having this problem? What are the others that are floating
 4 out there?

5 MR. GOBENA: I really can't talk about it in open
 6 court.

7 THE COURT: No, but the ones that have been opened.

8 MR. GOBENA: Oh, there's Dey and Roxane.

9 THE COURT: Yes, yes, right. So are you going to
 10 be adding new claims onto them?

11 MR. GOBENA: Well, I can't talk to that. Laurie
 12 Oberembt is here and is actually handling those two cases.
 13 She could probably address that for your Honor.

14 THE COURT: Are we going to have the same problem
 15 again?

16 MS. OBEREMBT: We don't have any plans to have the
 17 same problem again, your Honor.

18 MR. BREEN: Your Honor, there's also a separate
 19 complaint out of Boston where the relator has got -- it's a
 20 nonintervene case that was recently transferred to the MDL
 21 involving Abbott's PPD Division, correct.

22 MR. DALY: And that's going to be coming before
 23 you, Judge, with another motion.

24 THE COURT: What?

25 MR. DALY: They filed another duplicative action

1 here, even while they had this one in Florida.

2 THE COURT: What's PPD?

3 MR. DALY: That's our Pharmaceutical Products
 4 Division, Judge. That sells sort of branded drugs. The
 5 other one does the generic drugs.

6 THE COURT: So why isn't -- so that isn't part of
 7 this case?

8 MR. BREEN: No, your Honor. It was just
 9 transferred to the MDL recently. There's a motion to dismiss
 10 filed, and it's being briefed.

11 MR. GOBENA: It's another qui tam, your Honor.

12 MR. BREEN: I'm just making full disclosure as to
 13 the number of cases.

14 THE COURT: Well, what's this case about?

15 MR. GOBENA: It's another qui tam that was filed
 16 here in Boston. It involves completely different drugs and a
 17 different division within Abbott. The United States has
 18 declined to intervene on that case, so the relator is not
 19 proceeding, and I believe it's been transferred to the MDL.

20 THE COURT: I see, so it's a different division,
 21 different drugs.

22 MR. GOBENA: Different division, different drugs,
 23 different people selling them, different customer base.

24 THE COURT: So the new one is branded?

25 MR. BREEN: It is a branded drug, your Honor, but

1 they competed in the generic marketplace by marketing the
 2 spread, is the nature case.

3 THE COURT: And this case here in front of me
 4 mostly is generic?

5 MR. GOBENA: It's all generics, your Honor, and
 6 different kind of drugs. Our drugs in this case are
 7 injectable drugs. They're sold in sort of a --

8 MR. DALY: Saline, dextrose, sugar water, salt
 9 water.

10 THE COURT: So how do you deal with the median
 11 pricing issue?

12 MR. GOBENA: Well, that's an issue that we're
 13 evaluating right now, and, you know, we originally had -- we
 14 had a couple of theories that we're going to explore with our
 15 experts and ultimately probably put into our expert report,
 16 one of which is to argue that while there might be -- it
 17 might not be easy to show a clear line between Abbott's
 18 pricing and the effect on the median, the fact is that Abbott
 19 was marketing the spread on its drugs -- and we have
 20 documents to this effect -- knowing that it would affect the
 21 Medicaid reimbursements. And our argument is that by
 22 marketing the spread on Medicaid drugs, in effect, it's
 23 fraud-tainted Medicare claims because the scheme was not
 24 Medicare or Medicaid specific. It was geared towards getting
 25 government programs ultimately to pay for drugs. If we argue

1 that, then I think our damages might be -- the amount of the
 2 claims is tainted by taken by kickbacks -- Medicare claims
 3 were tainted by Medicaid kickbacks.

4 THE COURT: So it's not just a straight liquidated
 5 damage claim?

6 MR. GOBENA: No, no. And then the other thing --

7 THE COURT: Because unlike what I had in the other
 8 case, the False Claims Act is so much per claim. What is it?
 9 I don't even know.

10 MR. GOBENA: The claims are \$5,500 to \$11,000.
 11 Actually, from September 15, '99, till now, and the claims
 12 before that were \$5,000 to \$10,000. You're talking about the
 13 penalties?

14 THE COURT: Per claim.

15 MR. GOBENA: Per claim, yes. The other theory
 16 we're looking into is just seeing the effect that Abbott's
 17 prices had on the median price and determining damages based
 18 on that, kind of akin to what your Honor was doing in the MDL
 19 case. But I think it's fair to say, in our preliminary
 20 assessment of damages, that the vast majority of damages in
 21 our case are going to come from the Medicaid side where you
 22 don't have the median problem. The drugs were reimbursed on
 23 an NDC basis based on NDC and the AWP --

24 THE COURT: Don't you have MACs and FULs and all
 25 that stuff?

1 MR. GOBENA: No, actually not for -- for the most
 2 part, not for injectable drugs. If you ask me why, I can't
 3 give you an answer, even though these were generics, but you
 4 don't have a MAC or the FUL problem for the most part.

5 THE COURT: I thought this case for the generics
 6 would be easier because I don't have to deal with any of that
 7 liquidated damage amount.

8 MR. GOBENA: Well, no, it's more, I think, on the
 9 Medicaid side, it's a straight traditional damages theory.
 10 You're going to have AWP-based reimbursements, and you're
 11 going to have, you know, the differential between that and
 12 the actual, kind of like your brand case for Medicare.
 13 That's how it is for generics on the Medicaid side.

14 On the Medicare side, obviously you have the issue
 15 of the median, so the damages get a little bit more
 16 complicated. But, you know, like I said, I think it's fair,
 17 we're going to have, I think, substantial Medicare damages,
 18 but this is mostly a Medicaid damages case when we're talking
 19 damages.

20 THE COURT: Can I ask just going off the record for
 21 a minute.

22 (Discussion off the record.)

23 MR. DALY: Judge, I just want to understand where
 24 we are. They're going to file a motion for leave. Are we
 25 leaving the question of the relation back of the Aciclovir

1 claims to be hammered out in this motion in response?

2 THE COURT: No, you don't have to rebrief that.
 3 You've already briefed that to death.

4 MR. DALY: Okay.

5 THE COURT: I agree with you on your first point,
 6 which is a minor victory but a victory, which is, they need
 7 to move to amend.

8 MR. DALY: Right.

9 THE COURT: I have to say I'm somewhat persuaded,
 10 and I need to look at the documents, that if they didn't
 11 actually dismiss their claims but simply moved to adopt the
 12 government's, that there may be something there to intervene
 13 on, but I need to read the document myself.

14 MR. DALY: I know you will, but let me just read it
 15 to you: "Ven-A-Care moves pursuant to Rule 15, Federal Rules
 16 of Civil Procedure, for leave to amend its complaint as to
 17 Abbott only by adopting the United States' intervention
 18 complaint as Ven-A-Care's complaint against Abbott." And
 19 that's in Exhibit K to our motion to dismiss, to adopt it as
 20 Ven-A-Care's complaint against Abbott. I mean, I think if
 21 the Court were sitting here and you had two co-plaintiffs and
 22 one of them said, you know, "I'm adopting my co-plaintiff's
 23 complaint," you wouldn't be hearing from them two years
 24 later, "Oh, you know, I did that, but I've still got all
 25 these claims back here that I want to resurrect," and that's

1 what we're doing today.

2 THE COURT: It's extremely messy. It's extremely
 3 messy, and it's not clear for either of you.

4 MR. DALY: Judge, we have -- and I appreciate the
 5 Court's time today -- we have a sort of second phase of our
 6 argument, which is --

7 THE COURT: The NDCs.

8 MR. DALY: For all of them. And, you know, really
 9 it's a question of Exhibit A, if I may hand this up to the
 10 Court, which is --

11 THE COURT: You know, I feel less sympathetic to
 12 you when it's just, like, well, they mentioned one drug NDC
 13 but not the other drug NDC, because all NDC means is
 14 different amounts or how many milligrams in the dose.

15 MR. DALY: Well, I mean, here's my problem with
 16 that: Some of them are new drugs; some of them were added at
 17 different points in time. And I think the Court has made a
 18 variety of observations in various contexts that, you know,
 19 if I've learned anything in these cases, it's drug by drug,

20 NDC by NDC. And our first point here is under Baylor. I'm
 21 not going to reargue the Baylor motion that you did in Dey,
 22 but what's it going to relate back to? It ought to at least
 23 relate back to the first time that something was raised.

24 Otherwise --

25 THE COURT: The drug, the drug.

<p style="text-align: right;">Page 38</p> <p>1 MR. DALY: The drug.</p> <p>2 THE COURT: But not necessarily each NDC. That's</p> <p>3 slicing it too thin. I forget, there was another case where</p> <p>4 I didn't buy that argument, I don't remember which one it</p> <p>5 was, but you've got notice that this drug and this marketing</p> <p>6 with this drug; and if they didn't mention one NDC as opposed</p> <p>7 to another NDC, as long as it's the same drug, you've got</p> <p>8 fair notice of the claim.</p> <p>9 MR. DALY: Well, but there's quite a few in here,</p> <p>10 Judge, that are different drugs, completely different drugs.</p> <p>11 THE COURT: Completely new drugs?</p> <p>12 MR. DALY: Completely new drugs. If you look at</p> <p>13 Exhibit A, for example --</p> <p>14 THE COURT: What's a completely new drug?</p> <p>15 MR. DALY: When the government filed its first</p> <p>16 complaint, the one that was transferred to your Honor, if you</p> <p>17 look at the last page of this, Page 6 -- well, these are the</p> <p>18 ones, Judge, these are all J-Code drugs, and they had never</p> <p>19 been mentioned by anybody in any prior complaint.</p> <p>20 THE COURT: So the last four, is that the ones that</p> <p>21 are brand-new?</p> <p>22 MR. DALY: Yes. Yes, and that's important to us.</p> <p>23 And the one point I want to raise is --</p> <p>24 THE COURT: Wait. Is that right, they've never</p> <p>25 been mentioned in any drug, in any --</p>	<p style="text-align: right;">Page 40</p> <p>1 the Food and Drug Administration, and every one of these</p> <p>2 compounds and sizes and drugs -- you know this, Judge. And</p> <p>3 then the J-Codes are a group of those that are the same drug</p> <p>4 basically.</p> <p>5 THE COURT: It's a billing mechanism.</p> <p>6 MR. BREEN: Correct.</p> <p>7 THE COURT: J-Code is a billing mechanism, but if</p> <p>8 it's same drug, were the complaints -- were any new drugs</p> <p>9 alleged?</p> <p>10 MR. BREEN: For example, the Aciclovir was alleged</p> <p>11 in the '97 complaint.</p> <p>12 THE COURT: I'm asking, are there any new ones?</p> <p>13 MR. GOBENA: In the United States' either complaint</p> <p>14 or first amended complaint? All the drugs were either in the</p> <p>15 original complaint or are in the relator's second amended</p> <p>16 complaint which was filed by August 12, 1997.</p> <p>17 THE COURT: Is that right, and we have different</p> <p>18 billing codes and different NDCs codes?</p> <p>19 MR. DALY: Well, there are different NDCs, but</p> <p>20 there are different NDCs for a reason, Judge. I mean, not</p> <p>21 all saline products are the same. They're different drugs</p> <p>22 used for different purposes in different areas and different</p> <p>23 parts of the hospitals for different procedures. The same</p> <p>24 thing for Vanco, the same thing for sugar water. To claim,</p> <p>25 to say that all salines are the same, and if I sued you for</p>
<p style="text-align: right;">Page 39</p> <p>1 MR. BREEN: It's not right, your Honor. The J-Code</p> <p>2 nomenclature may have been new when we got into whatever</p> <p>3 amended complaint you're referring to, Jim, but the NDCs that</p> <p>4 those drugs relate to were part of the prior complaints. The</p> <p>5 drugs were alleged. It's the J-Coding itself --</p> <p>6 THE COURT: So what's an HCPCS?</p> <p>7 MR. BREEN: That's the HCPCS code, your Honor.</p> <p>8 That's J-Code.</p> <p>9 THE COURT: I know a lot now, but HCPCS is the same</p> <p>10 as J-Code?</p> <p>11 MR. GOBENA: Yes, your Honor. J-Code is a type of</p> <p>12 HCPCS code.</p> <p>13 THE COURT: So NaCl, is that salt?</p> <p>14 MR. BREEN: Salt.</p> <p>15 THE COURT: So that had been mentioned before?</p> <p>16 MR. BREEN: The NDC had, your Honor.</p> <p>17 THE COURT: Huh?</p> <p>18 MR. DALY: This isn't an NDC, though. That's my</p> <p>19 point. These are J-Codes. This is a whole new --</p> <p>20 THE COURT: I know, but is it the same drug?</p> <p>21 MR. BREEN: The same drug.</p> <p>22 MR. DALY: It's a different form of salt water or</p> <p>23 sugar water.</p> <p>24 MR. BREEN: It's not a different form, your Honor.</p> <p>25 It's a different code. The National Drug Code is issued by</p>	<p style="text-align: right;">Page 41</p> <p>1 saline, I can come in and sue you fifteen or twelve years</p> <p>2 later --</p> <p>3 THE COURT: But you haven't shown me that there's</p> <p>4 any difference. I mean, in other words, like, I can't</p> <p>5 remember now but -- I just tried this thing a year ago, but</p> <p>6 you would have the same drug that would be sold in different</p> <p>7 dosage amounts, and each one had a different NDC, but it was</p> <p>8 the same drug.</p> <p>9 MR. DALY: Well, that's what I'm trying to say,</p> <p>10 that they're not quite the same. I mean, you have topical</p> <p>11 solutions, you have injectables, you have bags. You have all</p> <p>12 sorts of different things.</p> <p>13 THE COURT: Some are pills, I understand, but it's</p> <p>14 the same compound.</p> <p>15 MR. DALY: Right.</p> <p>16 MR. GOBENA: Chemically equivalent, your Honor.</p> <p>17 THE COURT: Whatever it is, it's the same -- I</p> <p>18 don't know, I haven't been --</p> <p>19 MR. DALY: But my point with those is that those</p> <p>20 were never named in any complaint that the relator ever filed</p> <p>21 in the ten years prior to the government's intervention,</p> <p>22 so --</p> <p>23 THE COURT: When you say "those," you mean the</p> <p>24 NDCs?</p> <p>25 MR. DALY: These last three, the J-Codes that are</p>

1 involved here on the very last page.

2 THE COURT: But were the drugs that the billing
3 codes relate to named?

4 MR. GOBENA: Yes.

5 MR. DALY: Sugar water was named, one form of sugar
6 water or another was named in a prior complaint. My point
7 is, though, these suits are about NDCs and about drugs and
8 about specific payments made for specific drugs, not for salt
9 water generally. And if the government is intervening in
10 March of '06, they have to be intervening on claims that were
11 there to intervene on. And if there were no claims by the
12 relator on these, what is the government intervening on? The
13 government doesn't --

14 THE COURT: I understand that argument, and that's
15 the one that I'm still baffled by, which is what to do with
16 what you did way back when. And I must say, the concern I
17 have is, the default goes to the statute, and the statute
18 says "written consent of the Attorney General." So let's say
19 somebody drops something and you don't have written consent
20 of the Attorney General, what's the remedy?

21 MR. DALY: Judge, I think when you look at these
22 orders and see what was moved and that they moved together on
23 this, and that one the government opened up and permitted the
24 relator to come in and join their complaint as their
25 complaint, I don't know how much, other than somebody writing

1 a letter saying, "I hereby consent," I mean, that would be
2 consent in any other context.

3 THE COURT: Does it say "express consent in
4 writing"? It says the word "express"?

5 MR. GOBENA: I think it says "written consent" for
6 certain. I'm not sure about the "express" part. However, I
7 think that's the intent of the statute. Basically the
8 statute wants both the Court and the United States, the
9 Attorney General specifically, to weigh in on the disposal of
10 False Claims Act claims.

11 MR. DALY: But when the Court looks at this, and I
12 know it will, it does talk about dismissal of actions, not
13 the dismissal of claims. So I think that people can deal
14 with claims, but, you know, I think what's being dealt with
15 in the statute is: Don't make this thing go away without
16 telling me. And that didn't happen here. They did this
17 together. They opened it up, adopted each other, and sent it
18 up here to your Honor.

19 THE COURT: Well, it's a mess, and I hope I don't
20 have to do one of these again. Are you cleaning up
21 internally in the Department of Justice?

22 MR. GOBENA: Your Honor, you know, not to dump on
23 my colleague here, all we did, we intervened on the drugs we
24 intended to intervene on, and we're proceeding with them.

25 THE COURT: I'm just simply saying, the Department

1 of Justice -- I've been beating a drum, not with you but
2 forever up here in Boston -- it's got to happen faster and
3 cleaner.

4 MR. GOBENA: In terms of the interventions? Oh,
5 absolutely. This is a unique case, your Honor. I mean --

6 THE COURT: No, it isn't. That's the sad piece of
7 it. I totally understand Judge Jacobs' frustration in the
8 Second, and I've had a bunch of them up here too. So it's
9 something that I understand hugely about the resource
10 limitations, and how you don't get the FBI time and all that,
11 big drugs and you're fighting over very difficult issues, but
12 it can't be ten years. These are the kinds of issues that we
13 run into. And I guarantee you that short of genuinely newly
14 discovered evidence, I will not be allowing any other motions
15 to amend.

16 MR. GOBENA: We understand, your Honor. I mean,
17 obviously our preference would have been to have the
18 intervention done sooner, earlier in the process because, you
19 know, I've deposed people, or even that I've seen, I don't
20 know answers coming back at me. So I certainly understand
21 the Court's concern, and I think it's certainly the intention
22 of the Department's attorneys to move as quickly as
23 possible. This is a unique situation that was governed by
24 the number of defendants we had to investigate, and,
25 frankly, some obstinate practices on the part of the

1 defendants when it came to responding to document subpoenas,
2 Abbott being one of them.

3 MR. DALY: Judge, there is just one tiny point I
4 want to make on the relation back because I know I'm not
5 going to have a chance to do it later.

6 THE COURT: Yes, just one second.

7 MR. DALY: On the Baylor case, the Court when you
8 did the Dey decision, you said, you know, there might be
9 circumstances where Baylor might apply if the delay caused
10 such prejudice that it gets to almost a due process
11 constitutional. That's the Baylor issue we're raising for
12 your Honor when you get to that part of the relation back,
13 which is --

14 THE COURT: Yes, but you didn't really show that.

15 MR. DALY: Oh, but we did, Judge. We detailed it
16 time and time again. All of their witnesses are saying
17 either, "I don't remember," or, "I wish I had my documents
18 that I just told you are destroyed."

19 THE COURT: But they haven't shown me what they
20 would have remembered that would have made a difference.

21 MR. DALY: All of the questions that we asked them,
22 I mean, their witnesses, they had -- the government did not
23 issue a hold memo until 2007 in this case.

24 THE COURT: A what memo?

25 MR. DALY: A litigation, hold your documents, don't

1 destroy documents relating to X, Y, and Z, the thing that
 2 you're supposed to do, when they've had this litigation
 3 pending for twelve years.

4 THE COURT: What would you have found? I mean,
 5 that's why I wasn't persuaded. What would you have found if
 6 they had kept everything?

7 MR. DALY: Tom Scully, the head administrator of
 8 CMS, he had all kinds of files on --

9 THE COURT: But what would they have shown?

10 MR. DALY: They would have shown further knowledge
 11 and --

12 THE COURT: But we know that up the kazoo. The
 13 government knew. The government knew. The government knew.
 14 At least from all those OIG reports, they knew.

15 MR. DALY: Well, they knew more than that, though.
 16 They knew about not only generalized spreads, they knew
 17 specific spreads, they knew everything, and we were trying to
 18 improve our case.

19 THE COURT: Assume it's true.

20 MR. DALY: Well, if we can assume it's true, then I
 21 haven't been prejudiced.

22 THE COURT: I mean, they knew. They just, they
 23 were fighting, and they couldn't get it through Congress, and
 24 they couldn't get it through -- they knew as of, for sure,
 25 for sure, by 2001, but they pretty much knew by 1997 when you

1 had the Budget Act pass.

2 MR. DALY: Yes.

3 MR. GOBENA: And, your Honor, we're going to see,
 4 actually when we get to the summary judgment stage that while
 5 the agency might have known something about the drugs
 6 generally, it was trying to do its best to change things.
 7 And there were actually drug companies that lobbied Congress
 8 to block changes, Abbott being one of them. Actually that's
 9 one of the areas of discovery we're doing with the company
 10 right now is that they actually went to Congress people and
 11 tried to block the Secretary from having discretion to change
 12 drug --

13 THE COURT: But you'd be hard-pressed to say you
 14 didn't know.

15 MR. GOBENA: I understand, I understand, but
 16 there's knowledge, and it has to be knowledge and approval
 17 for the False Claims Act.

18 THE COURT: Right, knowledge is different from
 19 approval. I mean, that's why I wasn't persuaded because I
 20 went through that trial. They knew. Maybe they didn't know
 21 about Aciclovir. I don't know. That may be one of your
 22 points. But they knew that AWP was a phony, fictional price
 23 by the mid-1990s. They knew. So that's why I wasn't
 24 persuaded. They knew. What's her name, she was trying to
 25 change it? She kept getting shot down.

1 MR. DALY: Donna Shalala? Ms. Shalala?

2 THE COURT: Yes. They knew. Why they didn't do
 3 surveys, that would be an interesting question.

4 MR. GOBENA: Well, there's actually an answer to
 5 that, your Honor.

6 THE COURT: Which is?

7 MR. GOBENA: Which is that when the agency sought
 8 to do surveys, there was the Director of Payment Policy,
 9 Charles Booth, sent out a memo to carriers asking them to do
 10 surveys in 1994, right after the reg passed in '92. And the
 11 survey was actually killed by the Office of Management And
 12 Budget.

13 Now, what we've learned in discovery is that Abbott
 14 as well as two or three other companies met with
 15 representatives of ASCO, the American Society of Clinical
 16 Oncologists, to get together to develop a strategy to go out
 17 and reach out to OMB and have OMB kill the study. And in
 18 fact --

19 THE COURT: Maybe, but you are OMB. You know, it's
 20 one unitary Executive Branch government. I saw those
 21 documents in the last case. I know the pharmaceutical
 22 industry tried to, or at least some of them, tried to stop
 23 that survey; but at the end of the day, the person who
 24 stopped it was the federal government.

25 MR. GOBENA: Well, I mean, they raised issues about

1 the burden hours to various people to respond to the
 2 documents or whatever, but --

3 THE COURT: Sure, Small Business Regulatory Reform
 4 Act. I know that. I am simply saying that the federal
 5 government had the power to conduct the surveys; and whether
 6 it was HHS or OMB, the federal government didn't do it,
 7 although they knew AWP was a phony price. Now, what legal
 8 ramifications that has, I don't know, but I don't see the
 9 prejudice to you. I've got to go.

10 MR. GOBENA: One thing I'd ask.

11 THE COURT: What?

12 MR. GOBENA: We'd ask your Honor to reconsider the
 13 15(c)(1) ruling on --

14 THE COURT: Denied. You can't have it both ways.
 15 (c)(1) is different. See you later.

16 MR. DALY: Thank you, Judge. Thanks for your time
 17 today.

18 THE CLERK: Court is in recess.

19 (Adjourned, 4:55 p.m.)

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1 C E R T I F I C A T E
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3

4 UNITED STATES DISTRICT COURT)
5 DISTRICT OF MASSACHUSETTS) ss.
6 CITY OF BOSTON)
7
8

9 I, Lee A. Marzilli, Official Federal Court
10 Reporter, do hereby certify that the foregoing transcript,
11 Pages 1 through 49 inclusive, was recorded by me
12 stenographically at the time and place aforesaid in Civil
13 Action No. 01-12257-PBS, MDL No. 1456, In re: Pharmaceutical
14 Industry Average Wholesale Price Litigation, and thereafter
15 by me reduced to typewriting and is a true and accurate
record of the proceedings.

16 In witness whereof I have hereunto set my hand this
17 9th day of November, 2007.

18

19

20

21 /s/ Lee A. Marzilli

22 LEE A. MARZILLI, CRR
23 OFFICIAL FEDERAL COURT REPORTER
24
25